

Amendment and Response

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Serial No.: 09/600,432

Confirmation No.: 3387

Filed: October 2, 2000

For: PEPTIDES WITH β 1 INTEGRIN SUBUNIT DEPENDENT CELL ADHESION MODULATING ACTIVITY**Remarks**

The Office Action mailed February 18, 2004 has been received and reviewed.

Applicants acknowledge, with appreciation, the Examiner's allowance of claims 6 and 29. Claims 8-11, 23, 26-28, and 30 having been amended, claims 7, 24, 25, and 31-36 having been canceled, and claims 37-42 having been added, the pending claims are claims 6, 8-11, 23, 26-30, and 37-52. Reconsideration and withdrawal of the rejections are respectfully requested.

Support for the claim amendments and new claims is found throughout the specification. For example, support for new claims 37-52 is found on page 2, lines 9-17, page 5, lines 2-5, page 8, lines 21 -22, and page 11, lines 7-10 of the specification.

Examiner Interview

A telephonic interview was held between Examiner David Lukton and Applicants' Representative, Nancy Johnson, on February 23, 2004. In this interview the claim rejections under 35 U.S.C. §112, first paragraph, 35 U.S.C. §112, second paragraph, and 35 U.S.C. §102 were discussed. The Examiner is thanked for the courtesy of this interview.

The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claims 7, 9, 23, 24, and 27 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner asserted that the specification provides no guidance or direction for the modulation of β 1 integrin subunit dependent adhesion, when modulation is enhancement of cell adhesion. Applicants respectfully traverse this rejection. However, to expedite prosecution, Applicants have amended claims 9 and 23 to recite "inhibits," rather than "modulates." Claims 7 and 24 have been canceled. Withdrawal of this rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

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For: PEPTIDES WITH $\beta 1$ INTEGRIN SUBUNIT DEPENDENT CELL ADHESION MODULATING ACTIVITY**The 35 U.S.C. §112, Second Paragraph, Rejection**

The Examiner rejected claims 7-11 and 23-28 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This rejection is respectfully traversed.

Specifically, the Examiner asserted that claims 7-11 "are indefinite as to what first entity is adhering to what second entity" and claims 23-28 "are indefinite as to the manifestations of successful inhibition." Applicants respectfully disagree and submit that amended claims 8-10, 23 and 26-28 are not indefinite. Applicants submit that $\beta 1$ integrins are well known and well characterized in the literature, as is the role of $\beta 1$ integrins in mediating adhesion. Applicants further submit that assays for determining the inhibition of $\beta 1$ -mediated adhesion are well known to the skilled artisan. See, for example, Hynes, "Integrins: A Family of Cell Surface Receptors," Cell, 48(4):549-554 (1987); Ruoslahti, "Integrins," The Journal of Clinical Investigation, 87(1):1-5 (1991); and Springer, "Adhesion receptors of the immune system," Nature, 346(6283):425-434 (1990) (copies of which have been previously submitted). Examples of such assays include, for example, the assay for inhibition of $\alpha 4 \beta 1$ dependent cell adhesion (including the inhibition of $\alpha 4 \beta 1$ dependent Ramos cell adhesion to MICS-GST) described on page 11, line 6 to page 13, line 2 of the specification, the assay for the inhibition of $\alpha 5 \beta 1$ integrin dependent adhesion described on page 17, lines 1-25 of the specification, and the assay for the inhibition of $\alpha 2 \beta 1$ and $\alpha 3 \beta 1$ integrin dependent adhesion described on page 17, line 27-page 18, line 7 of the specification. Thus, Applicants submit that claim 8 (and dependent claims 9 and 10), drawn to "the peptide of claim 6, wherein said peptide inhibits $\beta 1$ integrin subunit dependent adhesion" is not indefinite. Inhibition of $\beta 1$ integrin subunit dependent adhesion is as determined by one of ordinary skill in the art using well known assays. Applicants further submit that claims 23 and 26-28 are not indefinite. The "manifestations of successful inhibition" are as determined by one of ordinary skill in the art using well known assays. Withdrawal of this rejection under 35 U.S.C. §112, second paragraph is respectfully requested.

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The 35 U.S.C. §102 Rejections

The Examiner rejected claim 30 under 35 U.S.C. §102(a) as being anticipated by Kubo (WO 97/34617). The Examiner also rejected claim 30 under 35 U.S.C. §102(b) as being anticipated by Stewart (U.S. Patent No. 4,923,963). Applicants respectfully traverse these rejections. As amended, claim 30 is drawn to "[a] peptide of no more than about ten amino acid residues, said peptide having the sequence Pro-Arg-Ala-Arg-Ile-Tyr (SEQ ID NO:24), Arg-Ala-Arg-Ile-Tyr (SEQ ID NO:25), Ala-Arg-Ile-Tyr (SEQ ID NO:26), wherein said peptide retains a C-terminal Ile-Tyr dipeptide sequence." Applicants submit that neither Kubo (WO 97/34617) nor Stewart (U.S. Patent No. 4,923,963) teach a peptide having SEQ ID NO:24, SEQ ID NO:25, or SEQ ID NO:26, wherein the peptide retains a C-terminal Ile-Tyr dipeptide sequence. Therefore, neither Kubo (WO 97/34617) nor Stewart (U.S. Patent No. 4,923,963) teach all elements of the claimed peptide and do not anticipate claim 30. Withdrawal of the rejections of claims 30 under 35 U.S.C. §102(a) and 35 U.S.C. §102(b) is requested.

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It is respectfully submitted that the pending claims 6, 8-11, 23, 26-30, and 37-52 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
MCCARTHY et al.

By

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17 day of May, 2004, at 8:55 A.M. (Central Time).

By:

Name:

Sandy Truehart
Sandy Truehart